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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,523	07/15/2002	Shigeo Takada	P22165	2401

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,523	TAKADA ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9 and 18-40* is/are pending in the application.

4a) Of the above claim(s) *18-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,39,40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed October 29, 2004 have been received and entered into the application.

Newly submitted claims 9 and 18-38 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims 9 and 18-38 are drawn to a **method** of suppressing appetite or promoting basal metabolism in a mammal comprising administering as an active ingredient, a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 9. This is invention is distinct and independent from the composition claims since the composition claims as claimed have different known effect and different statues in the pharmaceutical art since the composition is known to have different effects as an antitumor agent and it is not originally presented.

Since applicants have received an action on the merits for the originally presented invention (**composition**), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 9 and 18-38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action.

Claims 1, 9, 39 and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/466,541; 10/451,786; 10/070,434; 10/181,421; 10/070,435; and 10/451,787. Although the conflicting claims are not identical, they are not patentably distinct from each. First, it is respectfully pointed out that the preamble and the intended use recitations of the instant claims and those of the above referenced product claims are not afforded patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claims does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. Additionally, the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. Furthermore, regarding the product by process claims of the instant Application, it is respectfully pointed out that a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Thus,

since the instant claims and the above referenced application claims, all recite an agent comprising a mixture of cyclic and/or straight chain poly lactic acids having a condensation degree of 3 to 19, though the agents are recited for different intended uses, the instant claims are obvious over each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

Claims 1, 9, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Naganushi et al. (JP abstract 10130153 A) of record.

Naganushi et al. disclose an agent comprising a cyclic and straight chain mixed poly L-lactic acid having 3-19 degree of condensation as a main component, obtained by dehydrating and condensating L-lactic acid in a nitrogen gas atmosphere (inactive atmosphere) by reduction in pressure and heating by stages to give a reaction solution, drying soluble components of the reaction solution with ethanol and methanol under reduced pressure, carrying out a reversed phase ODS column chromatography, eluting the absorbed substance with a 25-50% aqueous solution of acetonitrile at pH 2.0 and collecting a fraction prepared by elution with 100% acetonitrile at pH 2.0. It is respectfully pointed out that the recitations "appetite suppressing agent" and "Food or drink composition for at least one of suppression of appetite, promotion of basal metabolism, improvement of obesity, suppression of excessive appetite or

enhancement of effect of kinesitherepy" have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. The Examiner respectfully points out instant claims 39 and 40 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on is method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

The term "consists substantially" in the instant claims is taken to mean that L-lactic acid units in the mixture of poly lactic acids are at least 70%, per the definition of pages 8-9 of the instant specification.

None of the claims are allowed.

Response to Arguments

Applicants' arguments, see **Response to Maintaining of Lack of Unity Requirement**, filed October 29, 2004, with respect unity of invention is present and the

requirement should be withdrawn have been fully considered and are persuasive. Therefore, the Lack of Unity Requirement has been withdrawn.

In response to the arguments regarding 35 U.S.C.102(b) rejection, Applicants essentially argue that claims are drawn to an appetite suppressing agent composition and the prior art (Naganushi) does not teach or suggest appetite suppression and although the intended use of the claimed composition is recited in the preamble of claim 1, the preamble in this case gives life, meaning and vitality to the claim. This is not persuasive since the prior art teaches same active agent having same condensation degree of 3-19 and same requirements as claimed by the Applicants. Therefore, the composition taught by Naganushi would inherently posses same effect of appetite suppressing effect as claimed by the Applicant.

The rejection of claims 3, 11 and 14 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicants amendment.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 6, 2004

SHENGJUN WANG
PRIMARY EXAMINER